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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,194	03/01/2000	LETTS L GORDON		3420

25270 7590 07/28/2005

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EXAMINER

STOCKTON, LAURA

ART UNIT PAPER NUMBER

1626

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/516,194

Applicant(s)

GORDON ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 11, 2005 and May 4, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8, 10-17, 19-31, 33-40, 104-106 and 117 is/are pending in the application.
- 4a) Of the above claim(s) 4-8, 10-17, 19-31, 33-40 and 104-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 3 is/are rejected.
- 7) ☒ Claim(s) 117 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

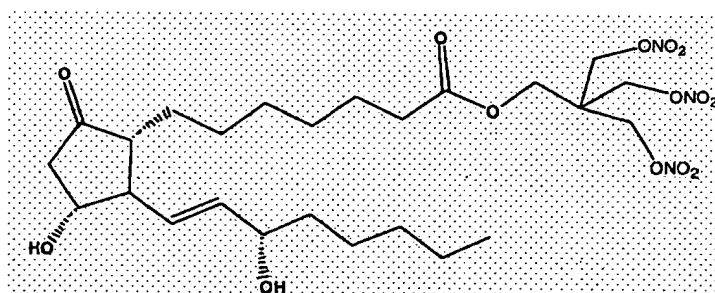
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DETAILED ACTION

Claims 2-8, 10-17, 19-31, 33-40, 104-106 and 117 are pending in the application.

Election/Restriction

Applicants' election with traverse of Group II and the species of Example 11 (reproduced below) on pages 52-54 of the instant specification, in the reply filed on October 15, 2004 was acknowledged in the previous Office Action.

Example 11

The requirement was deemed proper and was made FINAL in the previous Office Action. On

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April 15, 2005, Applicants petitioned the Restriction requirement of August 16, 2004.

On July 13, 2005, the Petition of the Restriction requirement of August 16, 2004 was granted to the extent that all of the compound groups (i.e., Groups I-XI) would be combined into one group, hereinafter known as modified Group I (claims 2, 3 and newly added claim 117, directed to compounds). The Petition grant also stated that an election of species was found to be proper and therefore, maintained and that the examiner is directed to follow the guidelines of M.P.E.P. 803.02. See bottom of page 4 and top of page 5 of the Petition grant of July 13, 2005.

Claims 2, 3 and 117 of elected modified Group I have been examined to the extent that they are readable on the elected species, Example 11. Since no prior art was found on the elected species, the search of the

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subject matter within elected modified Group I was expanded until prior art was found. Note, M.P.E.P. § 803.02. Also note the indicated examined subject matter (i.e., expanded search) outlined on page 2 of the previous Office Action dated January 13, 2005 (i.e., previous Group II).

Subject matter not embraced by the elected species of Example 11, the above identified expanded search, the below cited prior art, and claims 4-8, 10-17, 19-31, 33-40 and 104-106 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on October 15, 2004.

Response to Amendment

The amendment filed May 4, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- a) page 19, lines 18-32;
- b) page 20, lines 6-14; and
- c) page 28, lines 4-28.

Applicant is required to cancel the new matter in the reply, if any, to this Office Action.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No persuasive support can be found in the instant specification or the originally filed claims for R_e and R_f representing the group $-(C(R_o)(R_p))_k-T-Q$ nor for the individual definitions of R_o and R_p . Applicants state that support for this amendment to the claims is found

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on page 19, lines 18-32. However, page 19, lines 18-32 of the originally filed specification does not give support to this amendment since R_o and R_p are not mentioned anywhere on page 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

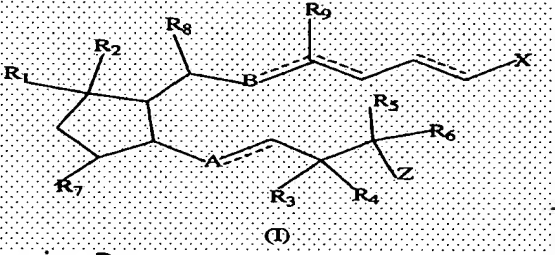
Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Del Soldato {WO 98/58910}.

***Determination of the scope and content of the prior art (MPEP
§2141.01)***

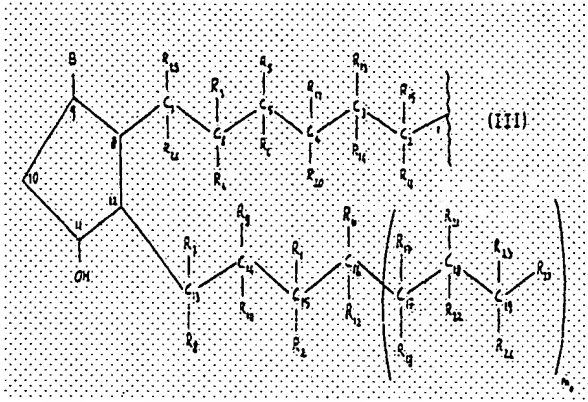
Applicants claim nitrostatic and nitrosylated prostaglandins. Del Soldato (pages 3-9) teaches nitrosylated prostaglandins that are structurally

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similar to the instant claimed compounds. See, for example, the table below.

Applicants' compounds	Del Soldato's compounds
<p>Formula (I)</p>  <p>(I)</p>	<p>formula (I) on page 3 A - X₁ - NO₂</p>
<p>R₁₁ is D₁; D₁ is D; D is K;</p> <p>K is W; E₁(CR₁(R))₁-E₂(CR₂(R))₁-W₂(CR₃(R))₁-W₁-E₃-W₃(CR₄(R))₁-T-Q</p> <p>Which is -CH₂-(COOH) Phenyl-CH₂-ONO₂</p>	<p>A = formula (II) - page 3 R(CR_aR_bO)_u(COX)_t u is zero; t is 1; X = O; X₁ is -CH₂-(COOH) Phenyl-CH₂O</p>

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<p>B is $-\text{CH}_2-$; R_8 and R_9 are each hydrogen; A is $-\text{CH}=\text{}$ R_3 is $-\text{OD}_1$ D_1 is hydrogen R_4, R_5 and R_6 are each hydrogen Z is butyl</p>	<p>R is formula (III)</p>  <p>$\text{C}_{13}-\text{C}_{14}$ (pages 4 and 7); m_o is 1 (page 4); R_2 is OH; R_{27} is CH_3 (page 7); All remaining R variables are either absent because of a double bond or represent hydrogen</p>
<p>R_1 and R_2 taken together is $=\text{O}_2$; R_7 is OD_1 D_1 is hydrogen;</p>	<p>B is $=\text{O}$ (pages 5 and 7)</p>
	<p>or see Example 1 on page 14</p>

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

***Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)***

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating impotence).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating impotence. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

Response to Arguments

Applicants' arguments filed April 11, 2005 and

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May 4, 2005 have been fully considered. Applicants argue that: (1) Del Soldato was previously cited by the Patent Office in the Office Action dated November 25, 2004 wherein the Office stated that the compounds in Del Soldato were excluded per the provisos found in the instant claims; (2) the compounds in claim 2 are structurally different from the compounds described by Del Soldato; and (3) there is no motivation or suggestion to make the compounds recited in instant claim 2 based on the compounds described in Del Soldato.

All of Applicants' arguments have been considered but have not been found persuasive. In the Office Action dated November 25, 2004, the previous Examiner did state that the Nitroprostaglandin compounds of Del Soldato were excluded by the proviso in the claims. However, upon reconsideration, instant claim 2 is obvious over Del Soldato. See the table above. Applicants in their arguments did not state how, for

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example, a compound outlined in the above table is circumvented by the various provisos in instant independent claim 2. Further, it is not agreed that the compounds of Del Soldato are structurally different than the instant claimed compounds. As shown above, there is an overlap of the compounds taught in Del Soldato and the instant claimed compounds.

Additionally, there is motivation in Del Soldato to make the compounds recited in instant claim 2. The motivation to make the claimed compounds derives from the expectation that the instant claimed compounds would possess similar activity to that which is claimed in the reference (e.g., treating impotence). In comparison of the definition of the instant K variable (found in the definition of the instant X variable) and the definition of the X_1 in Del Soldato, the X_1 in Del Soldato is of a much more limited scope. See, for example, the varying definitions of the instant W, E, R_e , R_f , a, b, p, c, x, d, etc. variables. If not for

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the provisos in instant claim 2, the Del Soldato reference would anticipate the claims. For all the reasons given above, the instant claimed compounds would have been suggested to one skilled in the art.

Allowable Subject Matter

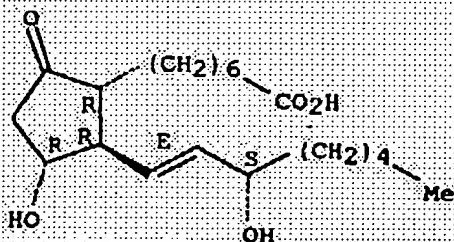
The elected species of Example 11 is allowable over the art of record.

Newly added claim 117 has been examined to the extent that claim 117 embraces the nitrosylated {NO} form of alprostadil. See below structural depiction of alprostadil. Therefore, claim 117 is objected to for containing non-elected subject matter. Claim 117 presented directed solely towards nitrosylated alprostadil would appear allowable over the prior art of record.

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L2 ANSWER 1 OF 1 REGISTRY COPYRIGHT 2004 ACS on STN
 RN 745-65-3 REGISTRY
 CN Prost-13-en-1-oic acid, 11,15-dihydroxy-9-oxo-, (11 α ,13E,15S)- (9CI)
 (CA INDEX NAME)
 OTHER CA INDEX NAMES:
 CN Cyclopentaneheptanoic acid, 3-hydroxy-2-(3-hydroxy-1-octenyl)-5-oxo-,
 (-)- (8CI)
 CN Cyclopentaneheptanoic acid, 3 α -hydroxy-2-(3-hydroxy-1-octenyl)-5-oxo-
 (7CI)
 OTHER NAMES:
 CN (-)-Prostaglandin E1
 CN 11 α ,15(S)-Dihydroxy-9-oxo-13-trans-prostenoic acid
 CN 11 α ,15 α -Dihydroxy-9-oxo-13-trans-prostenoic acid
 CN Alprostadil
 CN Alprox TD
 CN Caverject
 CN 1-PGE1
 CN 1-Prostaglandin E1
 CN Liple
 CN Lipoprost
 CN Minprog
 CN NSC 165559
 CN ONO 1608
 CN Palux
 CN PGE1
 CN Prostaglandin E1
 CN Prostandin
 CN Prostandin 500
 CN Prostlin VR Pediatric
 CN Prostivas
 CN SEPA-alprostadil
 CN SEPA-PGE1
 CN SEPA-prostaglandin E1
 CN Topiglan
 CN U 10136
 FS STEREOSEARCH
 DR 50-83-9, 22299-37-2, 50865-30-0
 MF C20 H34 O5

Absolute stereochemistry.
 Double bond geometry as shown.



PROPERTY DATA AVAILABLE IN THE 'PROP' FORMAT

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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This application contains claims and subject matter drawn to inventions nonelected with traverse. A complete reply, if any, to the final rejection must include cancellation of nonelected claims and subject matter (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton". The signature is fluid and cursive, with the first name "Laura" and last name "Stockton" clearly distinguishable.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

July 19, 2005